REMARKS/ARGUMENTS

The September 9, 2004 Office Action has rejected all claims under 35 U.S.C. § 102(b) as being anticipated by Mathieu, et al., U.S. Patent 5,665,387.

The Examiner notes that Mathieu teaches a method for treating diabetes and notes that "Mathieu is viewed as disclosing administration of 1,25-$(OH)_2D_3$ tablets to a subject in similar doses as instantly claimed."

Applicants dispute the Examiner's characterization of Mathieu, et al. as teaching successful oral dosing of vitamin D compounds for treatment of diabetes. Mathieu, et al., U.S. Patent '387, discloses examples of injections of 1,25-$(OH)_2D_3$ for treatment of diabetes. Applicants have enclosed a Declaration of Inventor Julia Zella demonstrating that Applicants attempted to replicate Mathieu's experiments and were unable to show that injection of 1,25-$(OH)_2D_3$ was effective in treatment of diabetes. Note paragraph 3 of Inventor Zella's statement where she notes that "our data showed similar disease instance in vehicle and 1,25-injected animals," Mathieu, et al. do not demonstrate Applicants claim of "reducing the risk of Type I diabetes in a predisposed human patient by up to 90%." Note that Applicants have described in their application that it was necessary to use oral administration for a successful outcome.

Although the Mathieu, et al. patent does suggest the use of tablets and oral compositions, these oral compositions and tablets are not actually demonstrated in the application. The Examiner seems to be arguing that Mathieu, et al. anticipates Applicants because Mathieu, et al. presents injection of 1,25-$(OH)_2D_3$ as a diabetes treatment and suggests use of oral administration. However, Applicants assert that because Mathieu, et al. does not demonstrate a successful treatment there can be no anticipation of the invention.

Anticipation under § 102 requires that "a claim in a patent application [lack novelty] if all of its elements are present in a single reference in the prior art."[1] Federal Circuit decisions repeatedly emphasize that anticipation is established only if the following are demonstrated: (1) all the elements of an invention as stated in a patent claim,[2] (2) are identically set forth,[3] (3) in a single prior art reference.

Anticipation also requires that a prior art reference adequately describe the invention in a patent application. The description, however, must be adequate to a person with ordinary skill in the art to which the invention pertains. "By the weight of authority, the description must enable such a person *not only to comprehend the invention but also to make it.*"[4] Thus, not only must a single prior art reference have all of the elements in a patent application, but the single prior art reference must also be enabling.

The Federal Circuit has most recently stated the enablement requirement in anticipation in *Transclean Corporation v. Bridgewood Services.*[5] Transclean was the assignee of a patent directed toward an automatic transmission fluid changing apparatus. Transclean brought an action against Bridgewood for patent and trademark infringement. Bridgewood, however, counter-claimed that it had not infringed Transclean's patent because it was anticipated by two prior art references - either a U.S. patent or a Japanese patent. The

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[1] Donald S. Chisum, *Chisum on Patents* Glossary - Scope (2004).
[2] *Eli Lilly & Co. v. Barr Laboratories, Inc.*, 251 F.3d 955, 970 (Fed. Cir. 2001), cert. denied, 122 S. Ct. 913 (2002) (stating that "a reference is anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently").
[3] *American Permahedge, Inc. v. Barcana, Inc.*, 857 F. Supp. 308, 318 (S.D. N.Y. 1994) (stating that "prior art anticipates an invention . . . if a single prior art reference contains each and every element of the patent at issue, *operating in the same fashion to perform the identical function as the patented product.* . . . Thus, any degree of physical difference between the patented product and the prior art, no matter how slight, defeats the claim of anticipation.") (emphasis added).
[4] Chisum, at § 3.04.
[5] *Transclean Corp. v. Bridgewood Servs.*, 290 F.3d 136 (2002).

district court found for Transclean; Bridewood appealed, maintaining that Transcleans' patent was anticipated by one of the two prior art references.

On appeal, the Federal Circuit affirmed the district court's decision and discussed the requirements of anticipation. It stated that under §102 "each and every limitation [must be] found either expressly or inherently in a single prior art reference. To anticipate, the reference must also enable one of skill in the art to make and use the claimed invention."[6]

The Federal Circuit applied these standards to the invention disclosed in the U.S. patent and found that it did not expressly or inherently enable one in the art to equalize overall fluid flow rate in the apparatus. The Federal Circuit also applied these standards to the invention disclosed in the Japanese patent and found that it did not expressly or inherently enable one in the art to equalize overall fluid flow rate in the apparatus. In conclusion, Federal Circuit decisions affirm that a prior art publication must be enabling in order to defeat novelty, that is, constitute an anticipation.

Applicants have submitted a Declaration showing that injection of 1,25-dihydroxyvitamin D3 is not effective to ameliorate diabetes symptoms. Therefore, the Mathieu, et al. reference cannot stand as a § 102 rejection.

[6] *Id.* at 1370.

Applicants believe that the claims are in condition for allowance and respectfully request allowance. Applicants have enclosed a Petition and Fee for Two Month Extension of Time. No other fees are believed necessary. However, if a fee is necessary please charge Deposit Account 17-0055.

Respectfully submitted,

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